UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA	:	NO. 3:16-CR-194
	:	
v.	:	(JUDGE CAPUTO)
	:	
FUHAI LI,	:	(ELECTRONICALLY FILED)
Defendant	:	

GOVERNMENT'S RESPONSE TO DEFENDANT'S MOTION TO PRECLUDE STEPHEN M. THOMAS, M.D. FROM PROVIDING EXPERT TESTIMONY AT TRIAL

NOW COMES, the United States, by and through Assistant United States Attorney, Michelle Olshefski, and files the following brief in response to the defendant's motion to preclude the testimony of Stephen M. Thomas, M.D. at trial.

I. INTRODUCTION

The defendant is charged in a 32-count Superseding Indictment. Counts 1 through 23 charge violations of 21 U.S.C. § 841(a)(1), for the defendant's distribution and dispensing of controlled substances outside the usual course of professional practice and not for a legitimate medical purpose. Count 24 charges a violation of 21 U.S.C. § 841(a)(1), for the defendant's distribution and dispensing of a controlled substance resulting in serious bodily injury and death of a person. Count 25 charges a violation of 21 U.S.C. § 861(f), for the defendant's distribution and dispensing of a controlled substance to a pregnant individual. Counts 26 and 27 charge violations of 21 U.S.C. § 856(a)(1), for the defendant's maintaining locations at 104 Bennett

Avenue, Suite 1B, Milford, Pennsylvania, and 200 3rd Street, Milford Pennsylvania, for the purpose of unlawfully distributing controlled substances. Counts 28 and 29 charge violations of 18 U.S.C. § 1957, for the defendant's engaging in monetary transactions in property derived from a specified unlawful activity. Counts 30 through 32 charge violations of 26 U.S.C. § 7201, for the defendant's tax evasion. The 27-page Superseding Indictment, which includes a detailed recitation of facts supporting the charges, also includes a forfeiture allegation seeking forfeiture of various property and U.S. Currency. (*See MDPA 3-cr-16-194, Doc. 47*).[1]

The defendant now seeks to exclude from trial relevant and proper testimony from an admittedly qualified pain management expert who will testify regarding the defendant's treatment of patients to aid in the jury's assessment of whether the defendant's prescribing was, as charged, outside the usual course of professional practice and not for a legitimate medical purpose.

The defendant appears to misunderstand the role of an expert report and wrongly seeks to limit relevant testimony based upon a very limited view of what constitutes a reliable opinion, a valid prescription, and a professional course of practice. The defendant's bases for his motion are transparently meritless and are

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[1] The defendant was first charged in a 24-count Indictment returned by a federal grand jury on July 20, 2016. (*See MDPA 3-cr-16-194, Doc. 1*). The tax evasions charges in the first indictment were identified as counts 22 through 24.

without legal and factual support. Further, as before in similar motions, the defendant misstates facts.

Additionally, the relief sought by this defense motion – a wholesale bar to testimony with which the defendant apparently disagrees – is inappropriate. Fundamentally, the defendant simply disagrees with Dr. Thomas' conclusions about the highly unprofessional and even dangerous practices that the defendant undertook and oversaw at his opioid-prescribing practice. This pre-trial effort should be rebuffed and his motion denied.

II. BACKGROUND FOR DR. THOMAS' EXPERT REPORTS

The Government first retained the services of Stephen M. Thomas, M.D. in or about December 2014 to examine the circumstances during which the defendant had issued an exorbitant amount of prescriptions for oxycodone at the highest dosage. Dr. Thomas reviewed some of the medical records maintained by the defendant regarding the issuance of those prescriptions. His preliminary conclusions assisted law enforcement in a probable cause finding for a search warrant affidavit.

On January 28, 2015, a search warrant was executed at the defendant's medical office and seizure of an electronic medical record keeping system occurred. On the same date, the defendant surrendered his DEA registration to interviewing DEA Agents. Before that time and towards the end of his practice, evidence revealed that the defendant had issued the same prescription, oxycodone at a high concentration, to the largest percentage of his patients.

Subsequent to the execution of the search warrant, Dr. Thomas was called upon again on two occasions. In or about July of 2016, the Government asked Dr. Thomas to review approximately 50 medical records, including multiple cases involving deaths, seized from the defendant's office for the purpose of offering an opinion as to the medical legitimacy of the prescribing of opioids associated with those files, and whether such prescribing habits occurred within the course of professional practice. In or about August of 2017, as the Government worked toward obtaining a Superseding Indictment, Dr. Thomas was asked to review additional medical records for the same purpose – to offer an opinion as to the medical legitimacy of the prescribing of opioids associated with those files, and whether such prescribing habits occurred within the course of professional practice.

As a result of the above requests, Dr. Thomas first authored a 29-page expert report dated July 6, 2016, and a supplemental expert report dated August 31, 2017. In the reports, Dr. Thomas details the methodology he employed in the assessment; the laws applicable to physicians licensed by the Commonwealth of Pennsylvania relied upon in reaching his conclusions; applicable federal regulations relied upon; and he references his reliance on various studies and research associated with pain management beginning in the mid-1980s. Additionally, Dr. Thomas offered his opinions based upon his education and experience as a Board Certified Anesthesiologist with a subspecialty in Pain Management; a Diplomat of the American Board of Anesthesiology and Pain Medicine; a Fellow of Interventional

Pain Practice; Certifications held in Controlled Substance Management, Coding Compliance and Practice Management, and as an Independent Medical Examiner; his more than 30 years as a practicing physician; as well as numerous highly regarded appointments, positions, certifications, lectures, publications, honors and awards.[2] In addition, Dr. Thomas has previously been qualified to testify as an expert in pain management in both federal and state courts throughout the country.

A close review of Dr. Thomas' reports evidences the thoroughness, specificity, and rationale for each conclusion reached. There is no question that Dr. Thomas could have written hundreds of pages about his review of the records, but that is not the purpose of an expert report. To be clear, the reports are not by themselves evidence nor does the Government contemplate that the reports will simply be provided to the jury. The purpose of the reports is to give fair notice to the defendant about expert opinions, as is required by Rule 16. The reports unquestionably comply with the Federal Rules and the Government should not be required to preview for the defendant how it is that the qualified expert will ably defend against the defendant's baseless attacks.

All of the defendant's attacks on Dr. Thomas' reports are of the type properly made during cross-examination of the expert, and not via a wholesale exclusion of

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[2] The curriculum vitae of Dr. Stephen Thomas was provided to the defendant in discovery.

relevant information from the jury's purview. Essentially, the defendant is seeking to preclude Dr. Thomas based upon the claim that Dr. Thomas' opinion is based upon only his subjective belief; a "questionable" methodology; a claim that Dr. Thomas did not rely on state standards in his assessment; and an allegation that Dr. Thomas does not cite any peer reviewed articles. The defendant's claims are without merit and factually wrong.

III. LEGAL DISCUSSION

In *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579, 590 (1993), the Supreme Court held that scientific evidence is admissible in federal court if it is "reliable."[3] The Court explained the reliability test as requiring "more than subjective belief or unsupported speculation." 509 U.S. at 590. It continued: "it would be unreasonable to conclude that the subject of scientific testimony must be 'known' to a certainty; arguably, there are no certainties in science.... But, in order to qualify as 'scientific knowledge,' an inference or assertion must be derived by the scientific

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[3] Reliability is not the only prerequisite for the admission of expert testimony. In addition, in order for an expert opinion to be admitted under Rule 702, the court must be satisfied by a preponderance of the evidence that the expert is qualified, and that the opinion is relevant to the matter at issue and will be helpful to the trier of fact. *United States v. Velasquez*, 64 F.3d 844, 849 (3d Cir. 1995). In this case, the qualifications of the Government's expert and the pertinence of his testimony is not disputed. The defendant, therefore, raises only the reliability of his analysis.

method. Proposed testimony must be supported by appropriate validation -- i.e., 'good grounds,' based on what is known." *Id.*

It is clear from the actual written reports that the conclusions reached by Dr. Thomas are not subjective in nature. Rather, his methodology is based upon an understanding of what renders a prescription valid under the laws of the Commonwealth of Pennsylvania and federal regulations, as well as his medical knowledge of chronic pain, controlled substances, and the interplay between the two.

The Controlled Substances Act (CSA) makes it unlawful "for any person knowingly or intentionally– to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance. 21 U.S.C § 841(a)(1). There is an exception, however, for registered practitioners. *See* 21 U.S.C. § 822(b). Registered medical professionals, including doctors and pharmacists, are authorized to issue prescriptions for or otherwise dispense controlled substances provided they do so in compliance with the requirements of their registration. 21 U.S.C. § 822(b).[4]

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[4] Issuing a prescription constitutes dispensing or distributing within the meaning of the statute. *See* 21 U.S.C. § 802 (10), (11). "[D]istribute' means to deliver (other than by administering or dispensing) a controlled substance or listed chemical." 21 U.S.C. § 802(11). "[D]ispense' means to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of a practitioner, including the prescribing and administering of a controlled substance." 21 U.S.C. § 802(10). A prescription "is the written representation of the drug and enables its possessor to claim physical custody and control over the drug prescribed." *United States v. Tighe*, 551 F.2d 18, 20 (3d Cir. 1977). "A person can violate 21

What the defendant fails to appreciate is the applicable standard to be applied when a doctor no longer operates with the immunity associated with a valid prescription. If the prescription is not valid, the defendant stands in the shoes of the stereotypical drug dealer on the street. In his reports, Dr. Thomas articulates that standard and specifically writes about where that standard is derived. It is a standard by which all physicians are guided.

As Dr. Thomas writes,

> "[T]he federal regulation, 21 C.F.R. § 306.04(a) – Purpose of Issue of Prescription, was the primary guide used in the medical record review. The regulation calls for the issuance of controlled substance prescriptions for a 'legitimate medical purposes.' The legitimacy of the medical purposes is established by the legitimacy of the rationale supporting the prescription with deference to the risks and benefits of the controlled substances prescribed. The Pennsylvania Controlled Substances, Drugs, Device and Cosmetics Act provided additional guidance as to the legitimate medical purpose of a prescription for controlled substances in that the substance must be provided in the usual course of the physician's professional practice, within the scope of a doctor-patient relationship, and in accordance with the accepted treatment principles of any responsible segment of the medical community. Under Pennsylvania statute and regulations, prescriptions provided outside of the usual course of professional practice, outside of the scope of the doctor-patient relationship, and/or not in accordance with the accepted treatment principles of any responsible segment of the medical community would be deemed illegitimate. Additionally, Pennsylvania Code, Tile 41 § 16.92 provides the documentation requirements for controlled substances for physicians in the Commonwealth."

U.S.C. § 841(a)(1) without actually distributing the controlled substances, but only by writing a prescription for their distribution." *United States v. Flowers*, 818 F.2d 464, 467 (6th Cir. 1987).

(Dr. Thomas report, 7/6/16, p. 3.)[5]

These are the legal foundations that are particularly relevant to the distribution and dispensing of controlled substances that were relied upon by Dr. Thomas in his review and assessment of the medical records and from which he drew his conclusions. Dr. Thomas' reports evidence a scientifically objective opinion based upon the practice of medicine, and specifically the practice of writing prescriptions for powerful opioid medications. When a practitioner issues prescriptions that are not valid, either to feed a patient's addiction or to cultivate a returning clientele, that is not the practice of medicine - that is drug dealing of the illegal kind. That is the essence of the defendant's criminal behavior in this case.

Daubert expanded, not restricted, the admissibility of expert opinion under Rule 702 by keeping with the Supreme Court's view of the "liberal thrust" of the Federal Rules and their general approach of relaxing the traditional barriers to

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[5] It is further clear that Dr. Thomas articulated the methodology he used: "The methodology used in reviewing the medical records was as follows: 1) each medical record submitted was read in its entirety; 2) the medical record was assessed for its completeness in outlining the indication for the prescription of the controlled substance, including diagnosis as ascertained through history, physical examination and diagnostic testing; 3) for chronic pain prescriptions the regularity of the prescribing patter was observed; 4) gross omissions from the medical record were discerned; 5) the indication or lack of indication for changes in dose were ascertained when possible; 6) efforts to monitor the medication-taking behavior of the patients were considered. (Dr. Thomas report, 7/6/16, p. 3.)

"opinion" testimony. *Id.* at 588, *quoting Beech Aircraft Corp. Rainey*, 488 U.S. 153, 169 (1988). Courts, and notably the Third Circuit, have been faithful to the Supreme Court's mandate to apply a liberal standard of admissibility under Rule 702. The Supreme Court's cases simply drew the line at what is colloquially referred to as "junk science," the attestations of purported experts without any reliable basis in fact or study. *Iacobelli Construction, Inc. v. County of Monroe*, 32 F.3d 19, 25 (2d Cir. 1994). *See Daubert* (questioning the reliability of testimony by a witness who simply "re-analyzed" 30 studies of over 130,000 patients, all of which found no link between use of Bendectin and the complained-of injuries, and reached a different conclusion); *General Electric Co. v. Joiner*, 522 U.S. 136, 145-46 (1997) (medical causation expert relied only on four epidemiological studies, which were either inconclusive or irrelevant to the pertinent issue); *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 154 (1999) (tire expert purported to state opinion regarding cause of tire failure, based solely on a visual examination of questionable value, and without consideration of substantial evidence contrary to his view).

Apart from such extreme circumstances, the Third Circuit has often held that the reliability "standard is not that high." *In re Paoli R.R. Yard PCB Litigation*, 35 F.3d 717, 745 (3d Cir. 1994) (commonly referred to as "*Paoli II*"). *Paoli II*, which presented a lengthy discussion of the *Daubert* standard in this Circuit, explained that the requirement of a showing of "reliability,"

> does not mean that plaintiffs have to prove their case twice -- they do not have to demonstrate to the judge by a preponderance of the evidence that the assessments of their experts are *correct*, they only have to demonstrate by a preponderance of evidence that their opinions are reliable.... Daubert states that a judge should find an expert opinion reliable under Rule 702 if it is based on "good grounds," i.e., if it is based on the methods and procedures of science. A judge will often think that an expert has good grounds to hold the opinion that he or she does even though the judge thinks that the opinion is incorrect.... The grounds for the expert's opinion merely have to be good, they do not have to be perfect. The judge might think that there are good grounds for an expert's conclusion even if the judge thinks that there are better grounds for some alternative conclusion, and even if the judge thinks that a scientist's methodology has some flaws such that if they had been corrected, the scientist would have reached a different result.

Id. at 744 (italics in original).

The Rules Advisory Committee, in amending Rule 702 in 2000, expressly adopted the *Paoli II* explanation. In addition, furthering the rule's liberal policy of accepting expert testimony, the Committee explained that even expert testimony "not rely[ing] on anything like a scientific method" may be admissible, if "it is properly grounded, well-reasoned, and not speculative."[6]

Paoli II was a toxic tort case brought by neighbors of a railyard where PCB's were used for a quarter century, who alleged that they suffered from a variety of physical ailments as a result. The Third Circuit held that the district court abused

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[6] The Third Circuit has relied on the 2000 Advisory Committee's note as "a useful consolidation of commentary and precedent" on the *Daubert* question. *United States v. Mitchell*, 365 F.3d 215, 234 n.14 (3d Cir. 2004).

its discretion in excluding all expert testimony offered on the basis of "differential diagnosis," where a physician undertakes to diagnose the cause of an illness by examining a patient, performing laboratory tests, and then considering any alternative explanations for the illness. The Court further held that the district court abused its discretion in excluding studies on animals of the effect of PCB's, given that "animal studies are routinely relied upon by the scientific community in assessing the carcinogenic effects of chemicals on humans." 35 F.3d at 780.

Notably, the Court found these areas of expertise sufficiently reliable, even while acknowledging that the accuracy of the witnesses' methods could not be known. With respect to differential diagnosis, the Court observed that a diagnosis regarding a particular individual cannot be empirically tested, but "[t]his merely makes it a different type of science than science designed to produce general theories; it does not make it unreliable science." *Id.* at 758. The Court held that a physician's opinion based on a faithful application of the method is admissible, because differential diagnosis "is a technique that has widespread acceptance in the medical community, has been subject to peer review, and does not frequently lead to incorrect results...." *Id. See also Heller v. Shaw Industries, Inc.*, 167 F.3d 146, 158 (3d Cir. 1999) (permitting introduction of "differential diagnosis" regarding the link between symptoms and exposure to a product without the need to prove "a statistically significant correlation.").

Following *Paoli II*, the Third Circuit repeatedly emphasized the limited nature of the reliability measure. *See, e.g., United States v. Mitchell*, 365 F.3d 215, 244 (3d Cir. 2004);[7] *In re TMI Litigation*, 193 F.3d 613, 692 (3d Cir. 1999); *Holbrook v. Lykes Bros. S.S. Co., Inc.*, 80 F.3d 777, 784 (3d Cir. 1996) ("The reliability requirement, however, should not be applied too strictly.... If the expert has 'good grounds' for the testimony, the scientific evidence is deemed sufficiently reliable."); *Oddi v. Ford Motor Co.*, 234 F.3d 136, 145-46 (3d Cir. 2000).[8]

The defendant's reliance on *Pritchard v. Dow Agro Sciences*, 430 Fed. Appx. 102 (3d Cir 2011) misses the mark. To compare the two case is akin to comparing apples and oranges. The issue in *Pritchard* was the proposed expert's stated reliance upon an unreliable study and nothing more. Essentially, the district court did not like how the proposed expert recalculated the study's conclusions in order to reach a

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[7] The defendant's failure to acknowledge or cite the *Mitchell* decision is telling. *Mitchell* is a recent and offers a thorough exploration of the *Daubert* issue in this Circuit, in which the Court rejected the effort of the defendant to establish the FBI's fingerprint identification method as unreliable.

[8] *See also United States v. Mathis*, 264 F.3d 321, 340 (3d Cir. 2001) ("experts who apply reliable scientific expertise to juridically pertinent aspects of the human mind and body should generally, absent explicable reasons to the contrary, be welcomed by federal courts, not turned away."); 2000 Advisory Committee notes to Rule 702 ("A review of the caselaw after *Daubert* shows that the rejection of expert testimony is the exception rather than the rule. *Daubert* did not work a 'seachange over federal evidence law,' and 'the trial court's role as gatekeeper is not intended to serve as a replacement for the adversary system.' *United States v. 14.38 Acres of Land Situated in Leflore County. Mississippi*, 80 F.3d 1074, 1078 (5th Cir. 1996).").

conclusion that benefited the Plaintiffs' interest. The proposed expert admittedly relied upon nothing else but the recalculation of conclusions from one study. The district court correctly ruled that the twisted conclusions of just one study relied upon by the proposed expert rendered his opinion less scientifically reliable. The Plaintiffs were left with nothing else to prove causation. There are no similarities, factual or legal, between the facts of *Pritchard* and the facts of this case.

Finally, it must be added that the district court's discretion in determining whether to permit expert testimony extends to the court's decision regarding whether and to what extent to even evaluate the evidence at a separate hearing, and to the detail with which to express its decision. The Third Circuit has repeatedly held that such matters lie within the district court's discretion, and that a court need not hold a hearing in every case nor provide any particular detail in its ruling.

For example, the *Mitchell* Court held that, given the clear admissibility of fingerprint analysis under the *Daubert* test, and the district court's considerable latitude in addressing a *Daubert* issue, a district court does not abuse its discretion by limiting a *Daubert* hearing to "novel challenges to the admissibility of latent fingerprint identification evidence -- or even dispensing with the hearing altogether if no novel challenge was raised." *Id.* at 246. *See also United States v. Mornan*, 413 F.3d 372, 380-81 (3d Cir. 2005) ("There is no requirement that the District Court always hold a *Daubert* hearing prior to qualifying an expert witness ...."), quoting *United States v. Evans*, 272 F.3d 1069, 1094 (8th Cir. 2001).

IV. CONCLUSION

For all the reasons stated herein, the Government respectfully requests that the Court DENY the defendant's motion in limine and request for a *Daubert* hearing.

Respectfully submitted,

DAVID J. FREED
United States Attorney

By: /s/ Michelle L. Olshefski
MICHELLE L. OLSHEFSKI
Assistant U.S. Attorney

Dated: March 13, 2018

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on the 13th day of March, 2018, I caused the foregoing "**Government's Response to Defendant's Motion to Preclude Dr. Stephen Thomas from providing Expert Testimony at Trial"** to be served upon Michael Weinstein, Esquire, counsel of record for the defendant, and that Attorney Weinstein is a filing user under the ECF system.

/s/ Michelle L. Olshefski
Michelle L. Olshefski
Assistant U.S. Attorney